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(54) RESPIRATORY SYSTEMS

(71) We, PHILIPS ELECTRONIC AND ASSOCIATED INDUSTRIES LIMITED, of Abacus House, 33 Gutter Lane, London EC2V 8AH, a British Company, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

The present invention relates to a respiratory system comprising a ventilator and a pressure controlled gas flow valve connected to an expiratory tube.

In certain patients requiring artificial ventilation, an important class being neonates exhibiting symptoms of idiopathic respiratory distress syndrome or hyaline membrane disease, it is found that it is beneficial to maintain the transpulmonary pressure during expiration, for example where there is a deficiency of pulmonary surfactant giving rise to a high surface tension in the alveoli. Under these circumstances there is a tendency for alveolar atelectasis to occur at the end of expiration when the difference between the airway and pleural pressure becomes low. Such atelectasis with its consequent decrease in arterial oxygen tension is detrimental to the patient and it is the purpose of the present invention to provide a means whereby these effects may be avoided during intermittent positive pressure ventilation of the patient. For the purpose of the present specification the end of the transpulmonary pressure during expiration will be hereinafter referred to as the "positive end expiratory pressure".

Preferably, a low resistance to the flow of air from the lungs should also be maintained until at least a positive end expiratory pressure is reached.

Prior to the present invention a positive end expiratory pressure was obtained in one method by submerging in water the end of an expiratory tube connected to a ventilating apparatus. A pressure in the lungs is then built up during the expiratory phase. The pressure may be adjusted by varying the depth of the end of the tube in the water until, to obtain a positive end expiratory pressure, the air from the patient's lung pushes the water in the tube aside to escape into the atmosphere.

In an alternative method a positive end expiratory pressure was obtained prior to the present invention by using a pressure relief valve which was actuated by a plunger, the pressure at which the valve operates being dependent upon the addition of one or more weights added to the plunger. However, such a plunger type pressure relief valve is not satisfactory in that the valve presents too large a resistance to the air flow from the patient's lungs.

Accordingly, it is one object of the present invention to provide a respiratory system which offers a minimal resistance to an air flow from the lungs until a predetermined positive end expiratory pressure level is reached.

It is another object of the invention to provide a respiratory system in which a pressure controlled gas flow valve, by its design in the choice of the relative surface area of a diaphragm to the cross-sectional area of an inlet aperture, enables a resistance to the air flow from a patient's lungs to be obtained for levels of pressure of said air flow below the positive end expiratory pressure. A diaphragm several times the cross-sectional area of the inlet aperture will operate a valve on relative proportionally small pressure changes, in which, for example, the smaller pressure change involved, the proportionally larger surface area of a diaphragm may be required. The respiratory system according to the present invention can give a quick build-up of pres-

sure to the positive end expiratory pressure level and therefore offer quick response to the operating conditions thereby maintaining a positive pressure of the gas under flow.

A further object of the invention is to provide a respiratory system including a pressure controlled gas flow valve which has a low resistance to the flow of air and which resistance may increase rapidly once the positive end expiratory pressure level is reached.

Respiratory systems according to the invention are also characterised by requiring no accessory equipment for their operation. They are noiseless in operation and may be calibrated to a range of positive end expiratory pressure levels and be easily preset to one particular positive end expiratory presure level in use.

According to the present invention there is provided a respiratory system which maintains a positive pressure of expired gas at the end of each respiratory cycle comprising a ventilator and a pressure controlled gas flow valve connected to the expiratory tube thereof, said valve comprising a chamber with a diaphragm which divides the chamber into two compartments, wherein pressure which is at least atmospheric pressure is adapted to be applied to one side of the diaphragm in a first of the compartments, the second compartment having an inlet aperture connected to said expiratory tube in the wall of the compartment opposite the diaphragm, an outlet aperture and a substantially flat stopper which passes through the diapragm and is connected thereto, said stopper normally sealing the outlet aperture but opening it when pressure due to the expiratory gas on the diaphragm in the second compartment is greater than the applied pressure on the side of the diphragm and the part of the stopper in the first compartment.

Preferably, the pressure on the diaphragm and the part of the stopper in the first compartment of the valve is at atmospheric pressure which pressure is maintained by an aperture in the first compartment which is open to the atmosphere. The pressure may be maintained other than at atmospheric pressure by a separate pressurized gas source which is maintained at an independent pressure level.

Alternatively, the pressure on the diaphragm and the part of the stopper in the first compartment may be controlled by an adjustable spring which acts on the stopper.

Preferably the diaphragm of the pressure controlled gas valve has a surface area at least twice the cross-sectional area of the inlet aperture. In one embodiment the diphragm for use in the pressure controlled gas valve for a respiratory system according to the present invention has a surface area of from two to twelve times the cross-sectional area of the inlet aperture.

The diaphragm may be formed from an inert flexible natural or synthetic sheet material. Suitable flexible natural or synthetic sheet materials arc natural or synthetic rubbers, plastics, rubberised fabrics, plasticised sheet materials or metal foils. The expression "inert" as referred in inert, flexible natural or synthetic sheet materials is understood to mean that an appropriate flexible sheet material is to be chosen which is inert or chemically unaffected by the air, gas or gases used in one or both compartments of the valve. Air, for example, when expired under conditions of anaesthesia, may contain organic compounds such as halogenated hydrocarbons which may decompose or perish certain flexible materials such as natural rubber. Materials such as neoprene rubber are used in such cases. Preferably, the diaphragm is fastened by its edges to the peripheral wall of the chamber to hermetically seal the first compartment from the second.

In one preferred embodiment of the respiratory system a pressure controlled gas flow valve has an adjustable spring-loaded plunger which acts on the stopper whereby a pressure on the spring is maintained by tensioning the spring by an adjustable fastening member. The adjustable fastening member may be pre-set to one of a number of positions, for example, by travelling down a helical groove to vary the pressure on the spring.

Preferably, the pressure controlled gas flow valve in use has a pressure maintained in the first compartment at atmospheric pressure. This pressure may be maintained in the first compartment by means of an aperture which is open to the atmosphere. The pressure may also be maintained from a separate gas source which, if desired, can be maintained at an independent pressure level at a pressure other than but above atmospheric pressure.

Further objects and advantages of the present invention will be apparent from the following description, reference being had to the following drawings wherein preferred embodiments of the invention are clearly shown:—

Figure 1 illustrates graphically a relationship between the pressure of air in a patient's lungs over the expiratory phase and the decreasing volume of air whilst the lungs are being ventilated with a ventilator apparatus,

Figure 2 is a side sectional view of a pressure controlled gas flow valve for a respiratory system according to the invention,

Figure 3 is a side sectional view of an alternative embodiment of a pressure controlled gas flow valve for a respiratory system according to the invention,

Figure 4 is a side sectional view of part of a pressure controlled gas flow valve for a respiratory system according to the invention, the part being indicated by a ringed insert in Figure 3,

Figure 5 is a perspective view from the top and side of a calibration lid of a pressure controlled gas flow valve for a respiratory system according to the invention, and

Figure 6 is a side view of a pressure controlled gas flow valve for a respiratory system according to the invention.

Referring now to Figure 1, the graph illustrated therein shows pressure P of air in a patient's lung whilst under artificial ventilation, plotted against decreasing volume V during the expiratory phase.

A positive end expiratory pressure level, P_e, is indicated and a typical level of pressure over an expiratory phase when using a pressure controlled gas flow valve for a respiratory system according to the invention is shown by straight line P_eO.

Thus, the pressure in the lungs remains substantially constant over the expiratory phase whilst the lung volume decreases to a standard residual amount. A low resistance to flow of air is therefore achieved when the desired level of pressure is reached and an undesirable resistive slope, as indicated by P_eR, is avoided.

Figure 2 illustrates a side sectional view of a pressure controlled gas flow valve for a respiratory system according to the invention which comprises a chamber divided into two compartments 1 and 2 by a diaphragm 3 in which compartment 1 has an inlet aperture 4, an inlet pipe 4', an outlet aperture 5 and an outlet pipe 5', and a stopper 6 attached to diaphragm 3 which can seal the outlet aperture 5, and in which compartment 2 has an aperture 7 open to the atmosphere at a pressure A. The diaphragm 3 is fixed by its peripheral edges to the wall of the chamber to hermetically seal compartment 1 from compartment 2. The pressure controlled gas flow valve is normally kept closed by gas pressure A acting on diaphragm 3 and attached stopper 6 via aperture 7 to force the stopper 6 into the outlet aperture 5, thereby blocking the passage of expired gas from inlet pipe 4' to outlet pipe 5'. To open the pressure controlled gas flow valve a relatively small increase in gas pressure in inlet pipe 4' transmits a relatively large lifting force to the diaphragm 3 in the direction of the arrows, thereby flexing the diaphragm and lifting the stopper 6 from the outlet aperture 5. On discontinuing the increased pressure in inlet pipe 4' the stopper 6 returns to close the outlet aperture 5.

Figure 3 illustrates a side sectional view of a pressure controlled gas flow valve for a respiratory system according to the invention which comprises a chamber divided into two compartments 1 and 2 by diaphragm 3 in which compartment 1 has an inlet aperture 4, inlet pipe 4', an outlet aperture 5, outlet pipe 5' and a stopper 6 attached to the diaphragm 3 which can seal the outlet aperture 5, and in which compartment 2 has an aperture 7 through which an adjustable spring-loaded plunger 8 acts on the stopper 6 to close the outlet aperture 5. The spring-loaded plunger 8 has a disc 9 on which a spring 10 rests. A recess 11 in a helically-adjustable core 12 holds the spring 10 in place. An adjuster capping body 13 has a helical groove cut in its inner bore (not shown) to allow the helically-adjustable core 12 to be located at a suitable position to tension the spring 10. The adjustable core 12 has spring-loaded pins 14, indicated in the insert of Figure 4, to locate it in the helical groove of the adjuster capping body 13, so that when the core 12 is rotated, it travels up or down the body of the capping body 13 to tension the spring 10.

Figure 4 illustrates a side sectional view of an insert of Figure 3 which shows one of the spring-loaded pins 14 which locate the adjustable core 12 in the helical groove (not shown) of the adjuster capping body 13.

Figure 5 illustrates a perspective view from the top and side of a calibration lid 15 of the pressure controlled gas flow valve according to Figure 3 in which calibration type markings are indicated on the lower side 15' of the lid 15 to match markings 13' on the adjuster capping body 13. In calibrating the valve a suitable range of calibrations is from 1 to 30 cms of H_2O and a preferred positive end expiratory pressure range for general use is from 2 to 12 cms H_2O. On calibration the calibrated lid 15 is locked in position by tightening screws 16.

Figure 6 illustrates a side view of a pressure controlled gas flow valve according to Figure 3 showing an inlet pipe 4', outlet pipe 5', adjuster capping body 13, calibrations markings 13' on the capping body 13, calibration lid 15, calibrations 15' on the lower side of on calibration lid 15, and chamber 17 indicated in two halves for fastening the edges of the diaphragm 3 by its edges on assembly.

With reference to Figures 3 and 5, one embodiment of the method according to the present invention is carried out by connecting an inlet tube 4' of a pressure con-

trolled gas flow valve according to the invention to an expiratory port before an expiratory valve of a ventilator and setting a calibration cap 15 to a desired positive end expiratory pressure level. On expiration the whole system pressurises up to the expiratory port, the total pressure on the side of the diaphragm in contact with the expired air being several times the pressure exerted from the plunger 8 and spring 10. A stopper 6 is therefore lifted to open aperture 5. With the expiratory valve open at the beginning of expiration the whole system starts to depressurise. When the correct positive end expiratory pressure level is reached, the stopper 6 blocks the outlet aperture 5 and the pressure is held at this level. The action is quick and responsive to relatively small changes in pressure in the expiratory tube and a small increase in pressure over the positive end expiratory pressure level opens the valve widely to the minimum resistance to respiration.

WHAT WE CLAIM IS:—

1. A respiratory system which maintains a positive pressure of expired gas at the end of each respiratory cycle comprising a ventilator and a pressure controlled gas flow valve connected to the expiratory tube thereof, said valve comprising a chamber with a diaphragm which divides the chamber into two compartments, wherein pressure which is at least atmospheric pressure is adapted to be applied to one side of the diaphragm in a first of the compartments, the second compartment having an inlet aperture connected to said expiratory tube in a wall of the compartment opposite the diaphragm, an outlet aperture and a substantially flat stopper which passes through the diaphragm and is connected thereto, said stopper normally sealing the outlet aperture but opening it when pressure due to the expiratory gas on the diaphragm in the second compartment is greater than the pressure applied on the side of the diaphragm and the part of the stopper in the first compartment.

2. A respiratory system according to Claim 1 in which the pressure on the diaphragm and the part of the stopper in the first compartment of the valve is maintained at atmospheric pressure by means of an aperture in the first compartment which is open to the atmosphere.

3. A respiratory system according to Claim 1 in which the pressure on the diaphragm and the part of the stopper in the first compartment is at a pressure other than at but above atmospheric pressure, which is maintained by a separate pressurizer gas source at an independent pressure or by an adjustable spring which acts on the stopper.

4. A respiratory system according to Claims 1 to 3 in which the diaphragm has a surface area at least twice the cross-sectional area of the inlet aperture.

5. A respiratory system according to Claims 1 to 4 in which the diaphragm has a surface area from two to twelve times the cross-sectional area of the inlet aperture.

6. A respiratory system according to Claims 1 to 5 in which the diaphragm is formed from an inert, flexible natural or synthetic sheet material fastened by its edges to the peripheral wall of the chamber.

7. A respiratory system according to Claims 1, and 3 to 6, in which an adjustable spring-loaded plunger acts on the stopper and wherein the pressure on the spring is maintained in a pre-set position by an adjustable fastening member.

8. A respiratory system comprising a ventilator and a pressure controlled gas flow valve connected to the expiratory tube thereof said valve being substantially as herein described with particular reference to Figures 2 to 6.

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1 447 091 COMPLETE SPECIFICATION
2 SHEETS This drawing is a reproduction of the Original on a reduced scale.
SHEET 1

Fig.1.

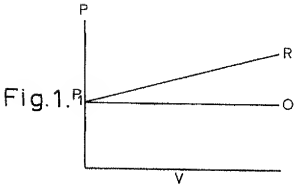

Fig.2.

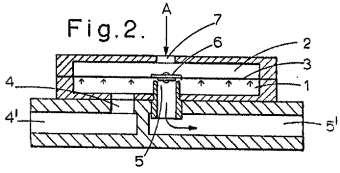

Fig.3.

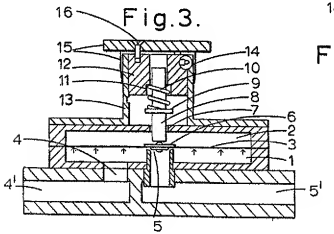

Fig.4

Fig.5.

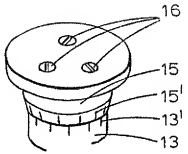

Fig.6.